Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	09/039,260	ABERG ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

All Participants:

(1) *L. E. Crane*.

(2) *Anthony M. Insogna*.

Status of Application: *related to 09/447,218 & 10/989,514: all cases discussed.*

(3) *S. Anna Jiang SPE*.

(4) *Hoon Choi & Robert Barker (Assignee Rep.)*.

Date of Interview: *13 December 2005*

Time: *2PM*

Type of Interview:
☐ Telephonic
☐ Video Conference
☒ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☒ No
If Yes, provide a brief description:

Part I.

Rejection(s) discussed:
All of record in all three cases

Claims discussed:
All of record in all three cases, independent claims in particular

Prior art documents discussed:
Vilani '716 patent and Berkow (Merck Manual)

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
See Continuation Sheet

Part III.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

(Examiner/SPE Signature)

(Applicant/Applicant's Representative Signature – if appropriate)

Continuation of Substance of Interview including description of the general nature of what was discussed:

Applicant's indicated that there had been a decision at the PTO BPAI wherein Mr. Insogna had successfully argued that inherency did not apply in the case wherein the metabolite of a known pharmaceutical was being claimed; i.e. the metabolite is separately patentable. Applicants also indicated that they intended to file an additional declaration in the instant cases, a complementary copy of which was supplied during the interview. Examiner's appreciate this gesture but the document is not yet officially of record so cannot be considered until it has been filed and made of record in the E-dan database of scanned documents for the instant case or cases. Applicant's representative made what appeared to be disparaging remarks directed to the newly submitted complementary declaration and when queried concerning what he had said, applicant's representative declined the opportunity to either repeat or explain his comments. And at the end of the interview applicant's indicated that the 10/989,514 case would probably be permitted to go abandoned and that the possibility of filing RCE's for the remaining cases was a possibility. When requested to comment on this possibility, examiner's indicated that any RCE's filed would be accepted but that no RCE's would be solicited from this or any other applicant by instant examiners. In a clarification applicant's noted that loratadine was the active ingredient in the pharmaceutical product sold as Claratin™ while the products sold as Clarinex™ contain the active ingredient descarbethoxyloratadine (DCL) which is the active ingredient in the instant claimed method of treatment and pharmaceutical composition claims at issue in this interview.

During the balance of the interview applicant's representative argued strenuously that the Storm declaration provided an adequate basis for a finding of allowability. Examiner's counter argued with the view that applicant's were misusing the opportunities afforded to introduce evidence to support arguments in obviousness rejections to alter inappropriately the policy of the PTO in re evidentiary requirements in medical claims. Alternatively examiner's noted that Storm's criticisms of the Villani reference amounted to an attempt to remove Villani from consideration as a reference in the instant case by casting doubt on its validity, a strategy which cannot be permitted except in the event that applicant's file a separate action requesting re-examination of Villani. In a discussion of the Storm declaration and examiner's comments on the declaration applicant's representative suggested that examiner's comments in re Storm in an Office action were prefaced by what applicant's suggested was merely sarcasm. Examiner's objected to this interpretation strenuously indicating that the complement to Dr. Storm as a knowledgeable person was intended as a complement, but that examiner's stood by their view that Storm was applying the wrong standard, and that applicant's were encouraged to submit declarations wherein the PTO standard provides the basis for arguments, as opposed to the FDA standard ("safe and effective") which Storm repeated referred to throughout his declaration.

In a discussion of the pharmaceutical composition claims in 09/039,260 and 10/989,514, applicant's asserted that their claims were patentably distinguishable over the Villani disclosure. Examiner's respectfully and strenuously disagreed, noting in particular column 11 at lines 29-33 of Villani (4,659,716) wherein the dosage regimen of " ... from 5 to 100 mg/day ..." included the further limitation permitting the dosage to be administered " ... in two to four divided doses to achieve relief of the symptoms," a reading which applicant's representative was unable to agreed permitted dosages to be as low as 1.25 mg/dosage. Examiner's insisted that this reading was valid and that this reading meant that the overlap between applicant's claimed range of dosage substantially overlaps with that disclosed by Villani in either solid dosage forms or transdermal dosage forms. No agreement or compromise on claim language was achieved during this discussion and examiner's seriously doubt that any compromise is possible.

In a discussion of the method of treating claims in 09/447,218, applicant's argued strenuously that the 103 rejection based on the combination of Villani and Berkow (Merck Manual) was insufficient and cited the references discussed in the Storm declaration (Michele and Parslew in particular) as providing serious doubt concerning whether one of ordinary skill would have been motivated to combine the two references as a basis for finding the instant claims obvious in light of the cited prior art. Applicant's argued that at the time of filing of the Villani application there was discussion in the pharmaceutical arts concerning possible side effects of DCL based on side effects of other antihistamines, a argument that examiner's found unconvincing because applicant's appeared to be making extrapolations equivalent to findings of guilt by association; i.e. no facts appeared to have directly implicated DCL as having disqualifying side effects and that in any case such arguments represent another example of Storm's mistaken application of the FDA "safe and effective" standard. Examiner's suggested that applicant's reliance on such arguments implied that applicant's were soliciting a rejection alleging inoperativeness under 35 U.S. Cl. §101, a suggestion which applicant's rejected out of hand as incorrect. Examiner's respectfully disagreed with these attacks

on the Office action and noted that Villani clearly disclosed and claimed pharmaceutical compositions DCL as an "antihistamine" with "anti-allergic" effects, that Berkow taught that antihistamines were useful in the treatment of urticaria (hives), and that Berkow's teaching that provides the ordinary practitioner with sufficient guidance to conduct routine experimentation in the search for an antihistamine appropriate to treat hives including a choice (DCL) taught and claimed by Villani. Examiner's also argued that the choice of the practitioner conducting routine experimentation is not constrained by a PTO utility standard or a PTO medical testing policy analogous to the FDA's "safe and effective" standard. and that applicant's reliance on the arguments of Storm appeared to be a flaw in their strategy because of Storm's excessive reliance on FDA standards. No agreement or compromise on claim language was reached during the extensive discussion of this issue.

NOTE: A copy of this interview summary in a different format but with the same text aside from this note was FAXed to applicant's representative Mr. Hoon Choi on December 16, 2005.